UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	)	**3:09-md-02100-DRH-PMF**
	)	**MDL No. 2100**

This Document Relates to: ***Jill Fender, as Special Administrator and Surviving Parent of the Estate of Melissa A. Fender, Deceased v. Bayer Healthcare Pharmaceuticals, et al.*** **Case No. 09-CV-20036-DRH**

MEMORANDUMUM AND ORDER

Regarding That part of the Motion which seeks to Exclude Testimony of Plaintiffs' Expert Witnesses David Green, M.D., Ph.D. and Mitchell Botney, M.D.

(Partial Ruling on Document No. 47)

I. INTRODUCTION

Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG ("Bayer") move, in part, to exclude the testimony David Green, M.D., Ph.D. and Mitchell Botney, M.D. as part of plaintiff's evidence. (Doc. 47).[1] Familiarity with

[1] Bayer also seeks summary judgment in this motion. The Court is deferring ruling on that part of the motion seeking summary judgment until a later date, but will determine the issues raised under *Daubert v. Merrell Dow Pharm.*,

the underlying proceeding is presumed. For the reasons that follow, Bayer's motion is **DENIED** on all grounds raised.

II. BACKGROUND

This Order is part of the Court's consideration of one of the bellwether cases in a multidistrict litigation (MDL) action relating to the manufacture, marketing, and sale of the prescription pharmaceuticals known as YAZ and Yasmin.[2] *Jill Fender, as Special Administrator and Surviving Parent of the Estate of Melissa A. Fender, Deceased v. Bayer Healthcare Pharmaceuticals, et al.* Case No. 09-CV-20036-DRH.

YAZ and Yasmin, are manufactured, marketed, and sold by Bayer, and are members of a class of prescription medicines known as combined hormonal oral contraceptives ("COCs"), which contain both an estrogen and a progestin component (Doc. 2090 p. 6). The vast majority of COC's, including YAZ and Yasmin, contain the same type of estrogen–ethinyl estradiol (EE). *Id.*[3] In contrast to estrogen, the progestins in COCs are of many types. The progestin in YAZ and Yasmin is a newer type of progestin known as drospirenone ("DRSP"). *Id.*

[2] This MDL relates to other oral contraceptives that, like YAZ and Yasmin, contain drospirenone. However, YAZ and Yasmin are the subject drugs involved in the pending bellwether trials.

[3] YAZ and Yasmin differ in their dosing schedule and the amount of estrogen they contain. The Food and Drug Administration (FDA) approved YAZ and Yasmin as oral contraceptives in 2006. The FDA subsequently approved YAZ and Yasmin as a treatment for moderate acne vulgaris in women who choose to use an oral contraceptive and as a treatment for premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive.

DRSP-containing COCs are known as "fourth-generation" COCs (classified by the type of progestin used). *Id*. at pp. 6-5. COCs containing earlier developed progestins are categorized as "first-generation," "second-generation," and "third-generation." *Id*. at p. 6. First-generation COCs contain the progestin norethynodrel. *Id*. Second-generation COCs contain the progestin Levonorgestrel ("LNG") and third-generation COCs contain several progestins, including desogestrel, gestodene, and norgestimate ("NGM"). *Id*.

It is generally accepted that there is an increased risk of venous thromboembolic (VTE) disease (disease relating to blood clotting in the veins) in COC users (Doc. 2102-14 p. 5; Doc. 2090-2 p. 2). It is also generally accepted that second-generation COCs (LNG-containing COCs) are considered to have a low risk for VTE disease (Doc. 2102-14 p. 6). Because the VTE risk associated with second-generation COCs is relatively low, LNG-containing COCs are often selected as a reference treatment in comparative studies evaluating whether there is an association between third-generation COCs and an increased risk of VTE disease (*See e.g.*, Doc. 2102-4) and in comparative studies evaluating whether there is an association between DRSP-containing COCs and an increased risk of VTE disease (*See e.g.*, Doc. 2102-14 pp. 5-6). In the mid-1990s, various reports indicated that users of third-generation COCs were at higher risk of VTE disease than users of second-generation COCs (Doc. 2090-2 p. 2).[4]

[4] Plaintiffs note that the third-generation COCs include labels advising doctors that "[s]everal epidemiologic studies indicate that third generation oral contraceptives . . .are associated with a higher risk of venous thromboembolism than certain second generation oral contraceptives."

At issue in this litigation is the safety of DRSP-containing COCs and whether the use of DRSP is associated with a higher risk of VTE disease. Specifically, plaintiffs contend that Bayer misrepresented or omitted facts pertaining to the safety and efficacy of YAZ and Yasmin. With respect to the safety of YAZ and Yasmin, plaintiffs contend that the DRSP component of the drugs is associated with an increased risk of VTE disease and of potentially life-threating thrombosis complications, including deep vein thrombosis (DVT) (a blood clot formation in one of the body's deep veins) and pulmonary embolism ("PE") (a clot formation that travels to the lungs).[5]

In this bellwether case, the plaintiff, Jill Fender, alleges that her daughter, Melissa A. Fender, suffered a fatal PE in July of 2007, as a result of taking YAZ for a period of approximately seven months. Melissa Fender was prescribed YAZ by a nurse practitioner after suffering break-through bleeding and diagnosis of ovarian cysts while taking other COCs. Before her death in July of 2007, Melissa Fender had taken other oral contraception medicines without experiencing any symptoms of PE. Melissa fender, shortly after a long road trip to and from New Jersey to her home in Iowa, experienced intermittent shortness of breath and chest pain. She was evaluated for these symptoms on July 21, 2007 and then collapsed during a walk on July 27, 2007, and was pronounced dead a short time later. The coroner later determined the cause of death was a PE. Plaintiff's

[5] Plaintiffs also contend that Bayer misrepresented the benefits of YAZ and Yasmin with respect to treatment of premenstrual syndrome ("PMS"), acne and premenstrual dysphoric disorder ("PMDD") and that YAZ and Yasmin are defectively designed because safer alternative designs exist. These contentions are not addressed by Dr. Green's proffered opinions.

experts, Dr. Green, and Dr. Botney, have each prepared reports with respect to the death of Melissa Fender (See Botney Report at Doc. 51, Ex.1 and Green Report at Doc. 51, Ex. 8). Based upon deposition testimony and their reports, Bayer seeks to exclude their testimony as experts. In particular, Bayer objects to each expert's opinion testimony that Melissa Fender's use of YAZ was a substantial factor in causing her fatal PE, and that if she had been using a different COC she would not have suffered the PE. In addition, Bayer seeks to exclude Dr. Botney's testimony that Melissa Fender experienced pain and suffering.

III. Legal Standard

FEDERAL RULE OF EVIDENCE 702, and *Daubert*, govern the admissibility of expert testimony. The *Daubert* standard applies to all expert testimony, whether based on scientific competence or other specialized or technical expertise. *Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S.137, 141 (1999)). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. *Daubert* clarified that Rule 702 charges the district court with the task of ensuring that expert testimony is both relevant and reliable. *Daubert*,

509 U.S. at 589. This is commonly referred to as the "gatekeeper" role of the court. *See, e.g. Banister v. Burton*, 636 F.3d 828, 831 (7th Cir. 2011)(where the court stated that "it is the district court's role to act as gatekeeper before admitting expert scientific testimony in order to 'ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'")

Resolution of an expert's credibility or the correctness of his or her theories under the particular circumstances of a given case is a factual inquiry, left to the jury's determination after opposing counsel has cross-examined the expert at issue as to the conclusions and facts underlying his or her opinion. *See, Walker v. Soo Line R.Co.*, 208 F.3d 581 589-90 (2000). Thus, "[i]t is not the trial court's role to decide whether an expert's opinion is correct. The trial court is limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound." *Id.* (citing *Kumho*, 526 U.S. at 159 (Scalia, J., concurring) (stating that the trial court's function under *Daubert* is to exercise its discretion "to choose among reasonable means of excluding expertise that is fausse and science that is junky")).

IV. ANALYSIS

The Court has previously determined that both Dr. Botney and Dr. Green are qualified to render expert opinions in this multidistrict litigation. Therefore, to the extent that Bayer again challenges their qualifications, that part of the motion to exclude is **DENIED.** The crux of Bayer's objection to these witnesses is

to their opinions that Melissa Fender would not likely have suffered a fatal PE if on a COC other than YAZ and that she suffered pain and suffering before her death. Bayer argues, in part, that because these opinions were not part of their respective reports, they cannot be the subject of testimony by the experts.

Unfortunately for Bayer's argument, the matters that they object to were opinions given by each witness in response to hypothetical questions posed by the defendant during the witnesses' depositions. Specifically, Dr. Botney was asked the following:

> Q. If Ms. Fender was [sic] taking a different estrogen-containing oral contraceptive at the time of her pulmonary embolism, do you have an opinion as to whether or not she would have had the pulmonary embolism?
> A. Now, you're asking about relative risk, and I'm not—I'm not prepared—I can't answer that question. I—I'm not competent to get into the topic of relative risks between various types of oral contraceptives.

(Botney Depo at 33-34). When asked the question later in his deposition, Dr. Botney stated:

> Q. . . .if Ms. Fender of [sic] not been switched to Yaz that she would have continued the rest of her life on this other birth control pill without a VTE—
> A. . . .More likely than not she would not have had a pulmonary embolism in the future.

Id. at 46-47. On re-direct, when asked if the use of YAZ, within a reasonable degree of medical certainty, caused her fatal PE, Dr. Botney replied, "I have no doubt about it." *Id.* at 48-49.

Similarly, Dr. Green's deposition included the following:

> Q. Do you recall earlier today that you were asked some hypothetical questions about a fictitious situation, asking you to speculate as to Ms. Fender being on a different contraceptive other than YAZ at the time of her death? Do you recall that series of questions?
> A. Yes, I do.
> Q. And in answering those questions, were you required to speculate?
> A. Yes.

(Green Depo. at 119). Unfortunately for Bayer's position, both of these "opinions" by Drs. Botney and Green were in direct response to hypothetical questions posed by counsel. The witnesses are permitted to respond to hypothetical scenarios. The defendant's challenge actually goes to the weight, not the admissibility of their testimony in the Fender case. The defendant is welcome to cross examine the witnesses and challenge the bases for their conclusions as part of the hypotheticals. In addition, defendant may tender experts of its own in contradiction to the position that Plaintiff's experts may take.

In addition, Bayer's challenge to the statement by Dr. Botney that the plaintiff suffered pain and suffering is likewise subject to challenge on cross-examination. As the Court previously noted: resolution of an expert's credibility or the correctness of his theories under the particular circumstances of a given case is a factual inquiry, left to the jury's determination. *Walker*, 208 F.3d at 589-90. Defendant may attempt to challenge that testimony, and those conclusion through the normal process of cross examination and the presentation of its own evidence. This is not, however, grounds for excluding a witness.

V. CONCLUSION

Accordingly, the Court **DENIES,** on all grounds raised**,** Bayer's motion to exclude the testimony of Plaintiff's experts, Mitchell Botney, M.D. and David Green, M.D., Ph.D. (Doc. 47) as set forth above.

IT IS SO ORDERED.

David R. Herndon
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Chief Judge
United States District Court

DATE: December 16, 2011